REMARKS

Claims 1-6 and 8-75 are pending in the application. Claim 7 has been cancelled and claims 65-72 have been withdrawn.

Claims 5, 6, 12, 26-29, 37, 38, 43 and 53-56 are identified as allowable but objected to as depending on rejected claims.

ARGUMENTS

Claims 1-4, 8-11, 13-15, 18-23, 32-36, 39-42, 44-50, 58, 61 and 64 have been rejected under 35 U.S.C. §102(e) as anticipated by U.S. Pat. No. 6,416,779 (D'Augustine). Each of these claims requires a ***suppository for a female urethra including a base member and a reinforcement*** projecting from the base member. The required suppository also includes ***a tapering meltable portion*** formed about the reinforcement. The meltable portion is received within the urethra. ***The base member of the required suppository is sized to prevent insertion of the base member into the urethra.***

D'Augustine discloses a tampon device (42; Fig. 6) adapted for vaginal insertion. The tampon device includes a cup-shaped porous foam portion (43) for delivering medication to the cervix. The materials disclosed for the porous foam portion are polyurethane, polyester, polyether and collagen. The foam portion of the tampon device is located adjacent a distal end portion of an absorbent tampon (45). A tube (44) extends between the foam portion and the distal end portion of the absorbent tampon and is centrally located to convey blood flow to the absorbent tampon. A proximal end (46) of the blood flow tube includes a plastic loop (47) for receiving a string (48) to provide for removal of an inserted tampon device.

I. The Claimed Invention is Not Anticipated by D'Augustine

The rejection of any of claims 1-4, 8-11, 13-15, 18-23, 32-36, 39-42, 44-50, 58, 61 and 64 based on D'Augustine is defective for multiple reasons. Firstly, the tampon device of

D'Augustine fails to include the required base member. As discussed above, the D'Augustine device is inserted into the vagina to deliver medication to the cervix. The plastic loop (*i.e.*, the purportedly comparable base member) of blood flow tube (44) is received in the vagina when the porous foam cup portion (43) and distal end of the absorbent tampon (45) are inserted. (See Figure 6). To the extent that the D'Augustine device may be compared to the urethral suppository device, ***the plastic loop is not sized to prevent insertion of the plastic loop*** into the vagina (*i.e.*, the receiver in which the device is inserted to deliver medication).

Secondly, the D'Augustine tampon device fails to show the required meltable portion formed about the reinforcement and tapering between its ends. The tapering element of the tampon device is the foam portion (43), which receives the blood flow tube (*i.e.*, the element purportedly reinforcing the foam portion). As discussed above, D'Augustine discloses that the foam portion may be made from polyurethane, polyester, polyether and collagen. ***None of the materials disclosed by D'Augustine for the foam portion (43) is meltable.*** The Examiner asserts that medication carried by the foam portion (43) may be meltable. (Page 2 of office action). Assuming, *arguendo*, that the medication was meltable, however, ***the foam portion (43) defining the tapered member for the tampon device will not melt.***

For the foregoing reasons, D'Augustine fails to disclose a device having the elements required by any of claims 1-4, 8-11, 13-15, 18-23, 32-36, 39-42, 44-50, 58, 61 and 64. D'Augustine, therefore, does not anticipate any of these claims.

Claim 9 depends from claim 1 and further requires that the ***reinforcement is embedded within the base member.*** The plastic loop (47) of the tampon device of D'Augustine (i.e., the purported base member) is located adjacent the end of the blood flow tube (44) but is not embedded within the blood flow tube. For this additional reason, in addition to the above reasons for claim 1, D'Augustine does not anticipate claim 9.

Claim 15 depends from claim 1 and requires that an end of the reinforcement opposite the base member ***extends outside the meltable portion.*** As shown in Figure 6, the end of the blood flow tube (44) of the tampon device of D'Augustine is surrounded by the tapering foam portion (43). For this additional reason, in addition to the above reasons for claim 1, D'Augustine does not anticipate claim 15.

Each of claims 18-21 depends from claim 1 and further requires that the ***reinforcement comprises one or more restraints*** along the portion of the length of the reinforcement on which the meltable portion is formed. Claim 19 requires that the restraints consist of ***protrusions and/or intrusions***. As shown in Figure 6, the blood flow tube (44) of the tampon device of D'Augustine does not include restraints and is, instead, uniform along the length that is surrounded by the tapering foam portion (43). For this additional reason, in addition to the above reasons for claim 1, D'Augustine does not anticipate any of claims 18-21.

Each of claims 22 and 23 depends from claim 1 and further specifies that the meltable portion of the urethral suppository include particular materials. As discussed above, D'Augustine discloses that the tapering foam portion (43) may be made from polyurethane, polyester, polyether and collagen. D'Augustine fails to disclose that the tapering foam portion be made from any of the materials specified in either claim 22 or claim 23. For this additional reason, in addition to the above reasons for claim 1, D'Augustine does not anticipate any of claims 22-23.

Each of claims 45-48 depends from claim 33 and further requires that the ***reinforcement comprises one or more restraints*** along the reinforcement. For the above reasons for claims 18-21, D'Augustine fails to anticipate any of claims 45-48.

Each of claims 49-50 depends from claim 33 and further specifies that the requires that the meltable portion of the urethral suppository include particular materials. For the above reasons for claims 22-23, D'Augustine fails to anticipate any of claims 49-50.

For at least the foregoing reasons, the rejection of claims 1-4, 8-11, 13-15, 18-23, 32-36, 39-42, 44-50, 58, 61 and 64 based on D'Augustine is improper and should be withdrawn.

II. The Claimed Invention is Not Obvious From D'Augustine

Claims 24, 25, 31, 51, 52, 57, 62, 63 and 73-75 have been rejected under 35 U.S.C. §103(a) as obvious based on D'Augustine. Each of these claims depends either from claim 1 or claim 33 and therefore requires a ***urethral suppository*** including a non-meltable base member and a non-meltable reinforcement projecting from the base member. The required

suppository also includes a meltable portion formed about the reinforcement and tapering between its ends. The meltable portion is received within the urethra. The base member of the required suppository is sized to prevent insertion of the base member into the urethra. Claims 24 and 51 require a diameter for a second end of the tapering meltable portion in the range of ***about 5 to about 12 millimeters***. Claims 25 and 52 require a diameter for a first end of the tapering meltable portion in the range of ***about 4 to about 10 millimeters***. Claims 31 and 57 require a length for the tapering meltable portion from ***about 2.5 to about 5.0 centimeters.***

The tampon device (Fig. 6) of D'Augustine is adapted for insertion into the vagina to deliver medication to the cervix. In contrast, the urethral suppository is adapted for insertion into the female urethra. The components for the urethral suppository are, accordingly, distinguished from those of the tampon device of D'Augustine in terms of size, shape, and function. The Examiner errs in asserting that it would have been obvious to modify the tampon device of D'Augustine in the manner claimed for the urethral suppository.

As discussed above, ***the base member of the claimed urethral suppository is sized to prevent insertion of the base member into the female urethra***. In contrast, the purported base member of the tampon device of D'Augustine (*i.e.*, the plastic loop receiving a string) is fully inserted into the vagina as shown in Figure 6. D'Augustine does not suggest modification of the plastic loop in the manner claimed. Assuming, *arguendo*, that the tampon device of D'Augustine was modified in size for receipt within the female urethra instead of the vagina, nothing would suggest further modification of the base member to prevent its insertion in the urethra in the manner claimed. In fact, ***D'Augustine teaches away*** by, instead, teaching attachment of a string to the plastic loop received in the vagina to facilitate its removal therefrom.

As also discussed above, the required suppository includes ***a tapering portion that is meltable***. D'Augustine teaches that the cup-shaped portion (43) is made from a non-melting material. Nothing in D'Augustine suggests modification in the claimed manner to form the cup-shaped portion (43) from a meltable material. In fact, ***D'Augustine teaches away*** by, instead, teaching that the non-melting cup-shaped portion carries medication that is delivered from the cup-shaped portion to the cervix.

Also, the teaching of D'Augustine fails to support the assertion that tube (44) of the disclosed tampon device is reinforcement. D'Augustine teaches that the tube (44) is located in the center of the foam portion (43) to "conduct blood flow to absorbent tampon (45)." (Col. 15, lines 10-12). There is no disclosure or suggestion in D'Augustine that the blood flow tube (44) reinforces the cup-shaped foam portion (43). The tampon devices of Figures 7 and 8 of D'Augustine, for example, include a cup-shaped foam portion but do not include the blood flow tube. Regarding reinforcement, ***D'Augustine teaches another way*** by teaching that the tampon device include a cylindrical cartridge container or inserter tube to assist in the insertion of the tampon device into the vagina. (Col. 16, lines 50-54).

Each of claims 24, 25, 31, 51, 52 and 57 specifies a dimensional size for the tapering meltable portion of the urethral suppository suited for a suppository adapted for insertion into the female urethra. The Examiner asserts that it would been obvious to "form the meltable portion having the dimensions as claimed, as would be necessary ***to fit inside the vagina of patients of various sizes***." (Page 4 of office action, emphasis added). Again, the claimed device is adapted for insertion into the female urethra. In contrast, the tampon device of D'Augustine is adapted for insertion into the vagina to deliver medication to the cervix. Notwithstanding variations in patient size, the Examiner errs in asserting that one skilled in the art would be motivated to provide a tampon device, which is inserted into the vagina to deliver medication to the cervix, with a cup-shaped portion (43) reduced in size to the claimed dimensions appropriate for insertion into the female urethra.

D'Augustine, therefore, fails to provide the necessary teaching of the claimed invention. The necessary teaching, lacking in D'Augustine, is only supplied impermissibly by hindsight use of applicant's disclosure.

For at least the foregoing reasons, the rejection of claims 25, 31, 51, 52, 57, 62, 63 and 73-75 based on D'Augustine is improper and should be withdrawn.

It is submitted that the application is now in condition for allowance. If the Examiner believes that direct communication would advance prosecution, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

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